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(54) **Balloon catheter device**

(57) A catheter configured to carry one or more stents and having an inflatable balloon for expanding a stent surrounding the balloon. The catheter is characterized in having a positioner for moving the one or more

stents relative to the balloon from a first position in which the stent does not surround the balloon to a second position in which the stent surrounds the balloon. Also disclosed is a method for deploying a stent at a desired location in the vascular system.

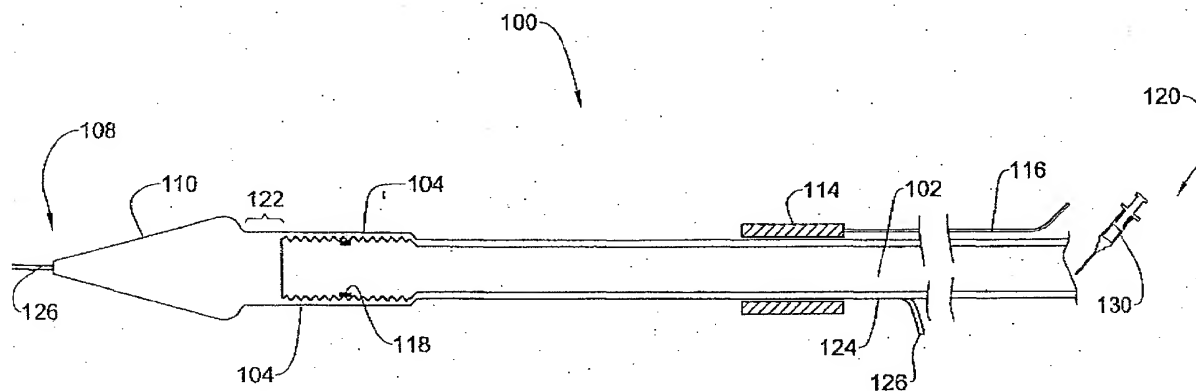


FIG. 1

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Description

FIELD OF THE INVENTION

[0001] This invention relates to catheters and more specifically to such catheters that are used to implant a stent in an artery.

BACKGROUND OF THE INVENTION

[0002] Blood vessels, and particularly arteries, may become stenotic or occluded due to various atherosclerotic processes. A stenotic artery may be treated by balloon angioplasty in which an inflatable balloon mounted on a catheter tip is inserted into the arterial system and navigated through the arterial system to the diseased artery. The balloon is then inflated by means of a pressurized fluid. This causes the balloon to press radially on the arterial wall so as to open the stenosis. A stent may be crimped onto the balloon before insertion so that when the balloon is inflated the stent becomes expanded. The balloon is deflated and withdrawn leaving the expanded stent in the artery. These and other similar methods are well known to the skilled man of the art.

[0003] It is often necessary to treat several stenoses in a single angioplastic session. For example, it may be necessary to insert a large diameter stent at one location, a small diameter stent at a second location and to perform a balloon angioplasty without a stent at a third location. This could be accomplished by sequential insertion and withdrawal of a catheter, the catheter being loaded each time with the appropriate stent prior to insertion. This however would cause much discomfort to the patient, prolongs the duration of the procedure and increases the chances of damaging a blood vessel.

[0004] U.S. Patent No. 6,027,519 discloses a catheter for deploying one or more stents. The stent has one or more individually expandable segments along its length. A stent, in its unexpanded state, is loaded onto each expandable segment of the catheter. The catheter is inserted into the vascular system and positioned with the first expandable segment in a stenosis. An axial force is then applied to the segment causing it to buckle outwards and expand the stent. The force is then removed causing the segment to unbuckle leaving the stent in its expanded state. The catheter is then navigated to another stenosis. This process is repeated until all of the stents have been deployed.

SUMMARY OF THE INVENTION

[0005] The present invention provides a catheter for deploying one or more stents in a cardiovascular system. The catheter is configured to carry one or more stents. Preferably, the catheter carries a plurality of stents. The stents may be of different or the same widths. An inflatable balloon is used to expand a stent surrounding the balloon. The catheter comprises a po-

sitioner for moving a stent relative to the balloon from a position in which the stent does not surround the balloon to a position that it does surround the balloon in order to prime the stent for expansion by the balloon. The phrase *"for moving a stent relative to the balloon"* includes two possibilities, i.e. moving the positioner relative to the balloon and moving the balloon relative to the positioner.

[0006] In one embodiment of the invention the positioner comprises an element configured to slide along the catheter and push the stents distally along the catheter so as to move a stent adjacent to the balloon into a position in which it surrounds the balloon. The sliding element is pushed along the catheter by means of a wire extending along the catheter from its proximal end to the sliding element. In this embodiment, the stents are deployed in the order in which they are carried by the catheter, starting with the stem closest to the balloon.

[0007] In another embodiment, the positioner comprises a flexible carriage configured to carry the one or more stents. The carriage is capable of sliding along the catheter in order to bring one of the stents from a position in which the stent does not surround the balloon to a position in which the stent surrounds the balloon. The carriage is moved in either direction along the catheter by means of a wire extending along the catheter from its proximal end to the carriage. It is also possible to position the stent opposite a desired location in the vascular system and slide the balloon through the carriage to a position opposite the stent. In this embodiment the stents may be deployed in the vascular system in any order.

[0008] In a third embodiment, the catheter comprises two positioners, one posterior positioner as described above in the first embodiment positioned posterior to the balloon, and a second anterior positioner positioned anterior to the balloon. In this embodiment, the anterior positioner may be distanced from the balloon so as to provide a storage space between the anterior positioner and the balloon. The balloon in this embodiment may be a conventional balloon used in balloon angioplasty. In this embodiment also, the stents may be deployed in the vascular system in any order, and may be of different lengths.

[0009] In use, the catheter is loaded with one or more stents and inserted into a vascular system. The catheter is navigated through the vascular system until the balloon or stent is positioned at a first desired location, typically the site of a stenosis. The stent or balloon is then moved by the positioner so that the stent surrounds the balloon and the balloon is inflated so as to expand the stent. The balloon is then deflated, leaving the expanded stent at the first desired location. This process may be repeated, each time deploying a different stent at a different location. After one or more of the stents have been deployed, the catheter may be removed from the vascular system.

[0010] The invention also provides a method for de-

playing a stent in a desired location of a vascular system comprising the steps of:

- (a) inserting a catheter according to the invention carrying one or more stents into the vascular system;
- (b) navigating the catheter through the vascular system until the balloon is positioned in the desired location;
- (c) moving a stent from a first position in which it does not surround the balloon to a second position in which it surrounds the balloon;
- (d) inflating the balloon so as to expand the stent; and
- (e) deflating the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

- Fig. 1** shows a catheter in accordance with one embodiment of the invention;
- Fig. 2** shows the catheter of Fig. 1 carrying stents;
- Fig. 3** shows the catheter at Fig. 1 inserted in a blood vessel;
- Fig. 4** shows the catheter of Fig. 1 with a stent surrounding a balloon on the catheter;
- Fig. 5** shows the catheter in Fig. 1 after inflation of the balloon;
- Fig. 6** shows a catheter in accordance with another embodiment of the invention;
- Fig. 7** shows the catheter of Fig. 6 carrying stents;
- Fig. 8** shows the catheter at Fig. 6 inserted in a blood vessel;
- Fig. 9** shows the catheter of Fig. 6 with a stent surrounding a balloon on the catheter;
- Fig. 10** shows the catheter in Fig. 6 after inflation of the balloon;
- Fig. 11** is a sectional side view of a catheter in accordance with another embodiment of the invention;
- Fig. 12** illustrates the operation of the embodiment illustrated in Fig. 11; and
- Fig. 13** illustrates another detail of the operation of the embodiment of Fig. 11.

DETAILED DESCRIPTION OF THE INVENTION

Example I

[0012] Fig. 1 shows a catheter **100** for deploying stents in accordance with one embodiment of the invention. The catheter **100** has a distal end **108** and a proximal end **120**. The catheter **100** comprises a flexible tube

102, which is connected to an inflatable balloon **104** proximate to its distal end. The balloon **104** is shown in the Figure in its deflated state. A radio-opaque marker **118** is located on the balloon wall. The catheter **100** has at its distal end **108** a tapered tip **110** that may be inserted into a stenosis in order to open the stenosis. A syringe **130** may be used to introduce a fluid into the tube **102** in order to inflate the balloon **104** as described in detail below.

[0013] A longitudinal shaft **124** in the wall of the tube **102** is configured to receive a guidewire **126** used in navigating the catheter in the vascular system. A neck region **122** of the tube **102** intervenes between the distal end of the balloon **104** and the tip **110**. The proximal end of the tip **110** is broadened to form a shoulder at the distal end of the neck region **122**. A sliding positioner element in the form of an annular sliding ring **114** is mounted on the tube **102** proximal to the balloon **104**. The ring **114** is slidable along the tube **102** by means of a wire **116** that extends along the length of the tube **102** from the proximal end **120** of the catheter to the ring **114**. [0014] The sliding ring **114** and the wire **116** form a positioner for moving a stent from a position in which it does not surround the balloon **104** to a position in which it surrounds the balloon **104**.

[0015] Fig. 2 shows the catheter **100** having a plurality of stents (three are shown in Fig. 2) **206a**, **206b** and **206c**, mounted on the tube **102** between the sliding ring **114** and the balloon **104**. The stents are separated from each other by separating rings **208a** and **208b**. The sliding ring **114** has been positioned so that the separating rings **208a** and **208b** and the stent **206** are contiguous with the balloon **104**. Each stent **206** bears a radio-opaque markers **210a**, **210b** and **210c**.

[0016] In use, the catheter **100** is introduced into the vascular system and navigated to a stenosis by methods well known in the art. Fig. 3 shows the catheter **100** after having been navigated through the vascular system and positioned inside a blood vessel **202**. The balloon is located opposite a stenotic region **204** of the blood vessel **202**. The wire **116** is used to slide the sliding ring **114** distally along the tube **102** so as to push the stents **206a**, **206b**, **206c**, distally. The sliding ring **114** is pushed distally along the tube **102** so that the stent **206a** is pushed over and around the balloon **104**, which is thereby brought into the lumen of the stent **206a**, and the marker **118** on the balloon coincides with the marker **210a** of the stent, as determined for example by x-ray angiography. Fig. 4 shows the stent **206a** surrounding the balloon **104**.

[0017] A fluid is then introduced into the tube **102**. The fluid passes through the tube **102** and inflates the balloon **104**. It will be understood that the balloon may be inflated by other conventional means, as are known in the art. Inflation of the balloon **104** expands the stent **206a** onto the stenotic region of the blood vessel **202**, as shown in Fig. 5.

[0018] The fluid is then withdrawn from the tube **102**.

Withdrawal of the fluid from the tube **102** causes the balloon to deflate. After deflation of the balloon, the stent **206a** remains *in situ* in its expanded state.

[0019] The catheter may then be navigated through the arterial system until the catheter is positioned with the balloon **104** at another stenotic region of a blood vessel. The sliding ring is pushed distally by the wire **116** so that the succeeding stent **206b** overlies the balloon **104** and the marker **118** coincides with the marker **210b** on the stent **206b**. The distal separating ring **208a** is pushed along the tube **102**, beyond the balloon **104** to the neck region **122** of the tube, where the separating rings are stored. The shoulder of the tip **110** retains the separating rings on the neck region. This process may be repeated until some or all of the stents **206** have been deployed. The catheter is then removed from the body.

Example II

[0020] Fig. 6 shows a catheter **600** for deploying stents in accordance with another embodiment of the invention. The embodiment of Fig. 6 has many components in common with the embodiment of Fig. 1, and similar components are identified by the same reference numeral in both embodiments.

[0021] The embodiment of Fig. 6 has a cylindrical carriage **605** mounted on the tube **102**. The carriage has a plurality of annular depressions (three are shown in Fig. 6) **610a**, **610b** and **610c** configured to receive a stent as described below. The depressions **610** all have the same length **A** as indicated in Fig. 6, which is essentially equal to the length of the balloon **104**. Between the depressions **610** are barriers **620a** and **620b**. The carriage **605** is made from an elastic material such as rubber. The carriage **605** is slidable along the tube **102** by means of a wire **116** that extends along the length of the tube **102** from the proximal end **120** of the catheter to the carriage **605**. The carriage **605** and the wire **116** form a positioner for moving a stent from a position in which it does not surround the balloon **104** to a position in which it surrounds the balloon **104**.

[0022] Fig. 7 shows the catheter **600** having a plurality of stents (three are shown in Fig. 7) **206a**, **206b** and **206c** mounted on the annular depressions of the tube **102**. The stents are separated from each other by the barriers **620a** and **620b**. In the present embodiment, the stents are of different lengths. However, they may also be of the same length. Each stent **206** bears a radio-opaque annular marker **210a**, **210b** and **210c**.

[0023] The catheter **600** is introduced into the vascular system and navigated to a stenosis by methods well known in the art. Fig. 8 shows the catheter **600** after having been navigated through the vascular system and positioned inside a blood vessel. **202**. The balloon is located within a stenotic region **204** of the blood vessel **202**. The wire **116** is used to slide the carriage **605** distally along the tube **102** so as to move the stents **206** distally. The carriage **605** is pushed distally along the tube **102**

until the balloon **104** is brought into the lumen of the stent **206a** and the marker **118** on the tube coincides with the marker **210a**, as determined for example by x-ray angiography. In a similar manner, the balloon may be slid within the carriage until it is positioned opposite the stent. Fig. 9 shows the stent **206a** surrounding the balloon. **104**.

[0024] A fluid is then introduced into the tube **102**. The fluid passes through the tube **102** and inflates the balloon **104**. Inflation of the tube **104** expands the portion of the carriage **605** surrounding the balloon **104** which in turn expands the stent **206a** onto the stenotic region of the blood vessel **202**, as shown in Fig. 10.

[0025] The fluid is then withdrawn from the tube **102** into the syringe **130**. Withdrawal of the fluid from the tube **102** causes the balloon to deflate. After deflation of the balloon, the stent **206a** remains in its expanded state.

[0026] The catheter is then navigated through the arterial system until the catheter is positioned with the balloon **104** in another stenotic region of a blood vessel. The catheter is then pushed distally by the wire **116** so that the stent **206b** overlies the balloon **104** and the marker **118** coincides with the marker **210b** on the stent **206b**. In this embodiment, the stents may be deployed in any order. This process may be repeated until some or all of the stents **206** have been deployed. The catheter is then removed from the body.

Example III

[0027] This example illustrates an embodiment which is an improvement over the embodiment described in Example I. With reference to Fig. 11, there is shown a catheter **700** having a distal end **108** and a proximal end **120**. As in Fig. 1, the catheter **700** comprises a flexible tube **102**, which is connected to an inflatable balloon **704** proximate to its distal end. A radio-opaque marker **118** is located on the balloon wall. The catheter **700** has at its distal end **108** a tapered tip **110**, but unlike in Example I, there is no neck region, and the tip is not enlarged. The balloon in this embodiment may be a conventional inflatable balloon used in balloon angioplasty.

[0028] As in Example I, a guidewire **126** extends along the tube **102**, exiting at the distal end **108** of the catheter. An anterior positioner in the form of a perforated sphere **706** is fixed to the guidewire anterior to the balloon **704**, e.g. the guidewire passes through a bore channel extending through the sphere. The diameter of the sphere is slightly larger than the diameter of the retracted stents which are mounted on the catheter. The purpose of the sphere will be explained below.

[0029] The catheter **700** has a sliding ring **114** (being the posterior positioner) and a plurality of stents (three are shown in Fig. 11) **206a**, **206b** and **206c**, mounted on the tube **102** between the sliding ring **114** and the balloon **704**. While the anterior stents are generally of the same length, the posterior stent may be longer or

shorter. In the illustrated embodiment, the posterior stent **206c** is shorter than the other stents. Each stent **206** bears at least one radio-opaque marker **210a**, **210b** and **210c**, respectively. The stents are separated by separating rings **708a** and **708b** which are of the same length as the anterior stents. An anterior ring **710** is positioned between the most anterior stent **206a** and the balloon **704** and protects the distal edge of the anterior stent. This anterior ring may be shorter than the separating rings.

[0030] The operation of this embodiment may be understood with reference to Fig. 12. As in Example I, the wire **116** is used to slide the sliding ring **114** distally along the tube **102** so as to push the stents **206a**, **206b**, **206c**, distally. The sphere **706** is distanced from the distal end **108** of the catheter by pushing the guidewire **126**, thus providing free guidewire **712** on which components of the catheter may be stored. In Fig. 12, it may be seen that the anterior ring **710** and the separating ring **708a** have been pushed beyond the balloon **704** and onto the free guidewire **712**. The anterior stent **206a** (not shown) has been expanded and deployed within the blood vessel wall, and the middle stent **206b** is mounted on the balloon **704**, ready to be expanded. The radio-opaque marker **210b** of the stent **206b** is positioned opposite the radio-opaque marker **118** of the balloon **704**.

[0031] Thus, this embodiment also differs from that of Example I in having more room to store the separating rings. In addition, all of the mounted stents and rings may be moved distally and proximally by pulling and pushing the anterior and posterior positioners, being the sphere **706** and sliding ring **114**, respectively, so that the stents may be deployed in any order. This differs from Example I where the stents were required to be deployed in the order in which they were placed on the catheter.

[0032] Fig. 13 shows the catheter after the 2 anterior stents **206a** and **206b** (not shown) have been deployed, and the anterior **710** and separating **708a** & **708b** rings are positioned on the free guidewire **712** between the sphere **706** and the balloon **704**. It may be seen that the separating rings have annular protrusions **714** protruding from their outer surface. The purpose of these protrusions is to protect the blood vessel inner wall from being injured by the stents as the catheter travels through the vessel. The posterior stent **206c** is mounted on the distal half of the balloon **704**, while the anterior portion of the sliding ring **114** envelops the proximal end of the balloon. Thus, when the balloon is inflated, only the distal half expands (since the sliding ring resists the pressure of the balloon), expanding the stent **206c** and deploying it in the blood vessel.

Claims

1. A catheter configured to carry one or more stents and having an inflatable balloon for expanding a

stent surrounding the balloon, the catheter being characterized in having a positioner for moving said one or more stents relative to said balloon from a first position in which a stent does not surround the balloon to a second position in which the stent surrounds the balloon.

2. The catheter according to Claim 1 configured to carry a plurality of stents.
3. The catheter according to Claim 2 wherein the stents may be deployed in a blood vessel in any order.
4. The catheter according to Claim 1 wherein the positioner comprises a sliding element configured to slide longitudinally along the catheter and push the one or more stents distally along the catheter so as to move a stent adjacent to the balloon into a position in which it surrounds the balloon.
5. The catheter according to Claim 4 wherein the sliding element is attached to a wire extending longitudinally along the length of the catheter and the sliding element slides along the catheter in response to a longitudinal movement of the wire.
6. The catheter according to Claim 1 wherein the positioner comprises a carriage configured to carry the one or more stents and to slide longitudinally along the catheter relative to the balloon so as to move the stent from the first position to the second position.
7. The catheter according to Claim 6 wherein the carriage is attached to a wire extending longitudinally along the length of the catheter, and the carriage slides along the catheter in response to a longitudinal movement of the wire.
8. The catheter according to Claim 1 comprising two positioners, a posterior positioner positioned posterior to the balloon and an anterior positioner positioned anterior to the balloon.
9. The catheter according to Claim 8 wherein said anterior positioner may be distanced from the balloon so as to provide a storage space between the anterior positioner and the balloon.
10. A method for deploying a stent in a desired location of a vascular system comprising the steps of:

- (a) inserting a catheter according to Claim 1 carrying one or more stents into the vascular system;
- (b) navigating the catheter through the vascular system until the balloon is positioned in the de-

sired location;

(c) moving a stent from a first position in which it does not surround the balloon to a second position in which it surrounds the balloon;

(d) inflating the balloon so as to expand the stent; and 5

(e) deflating the balloon.

11. The method of Claim 10 further comprising a step of: 10

(a) repeating steps (b) to (e) a number of times, and

(b) withdrawing the catheter from the vascular system. 15

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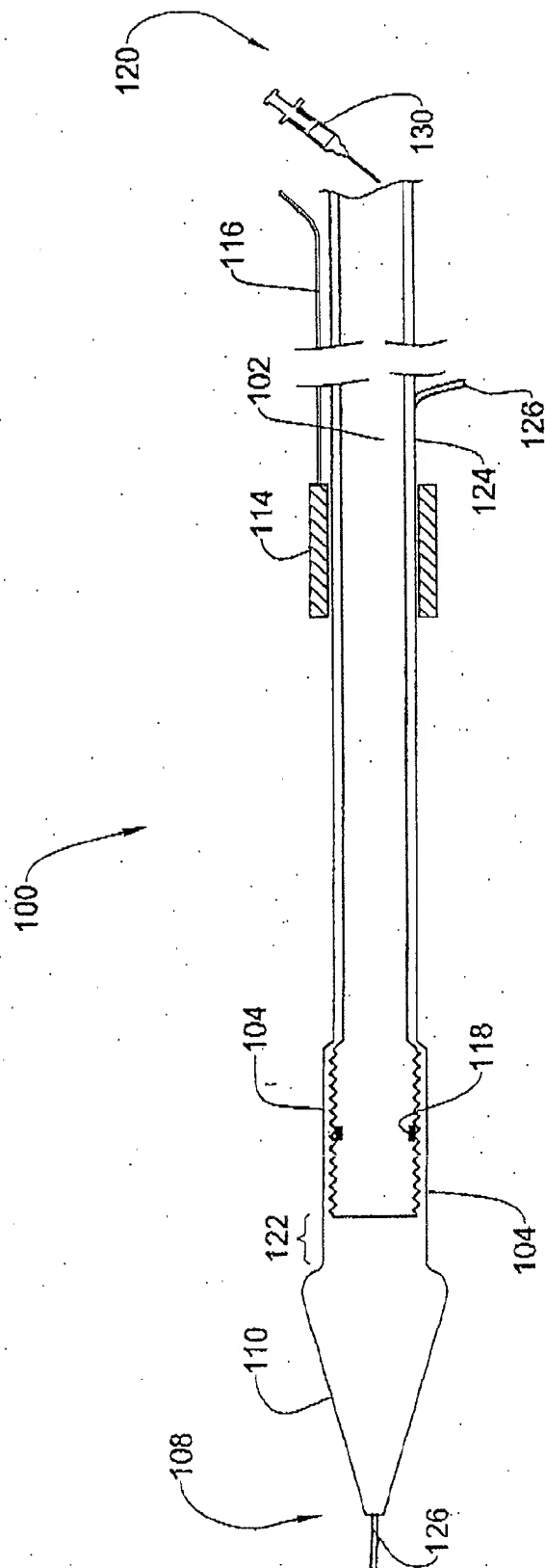


FIG. 1

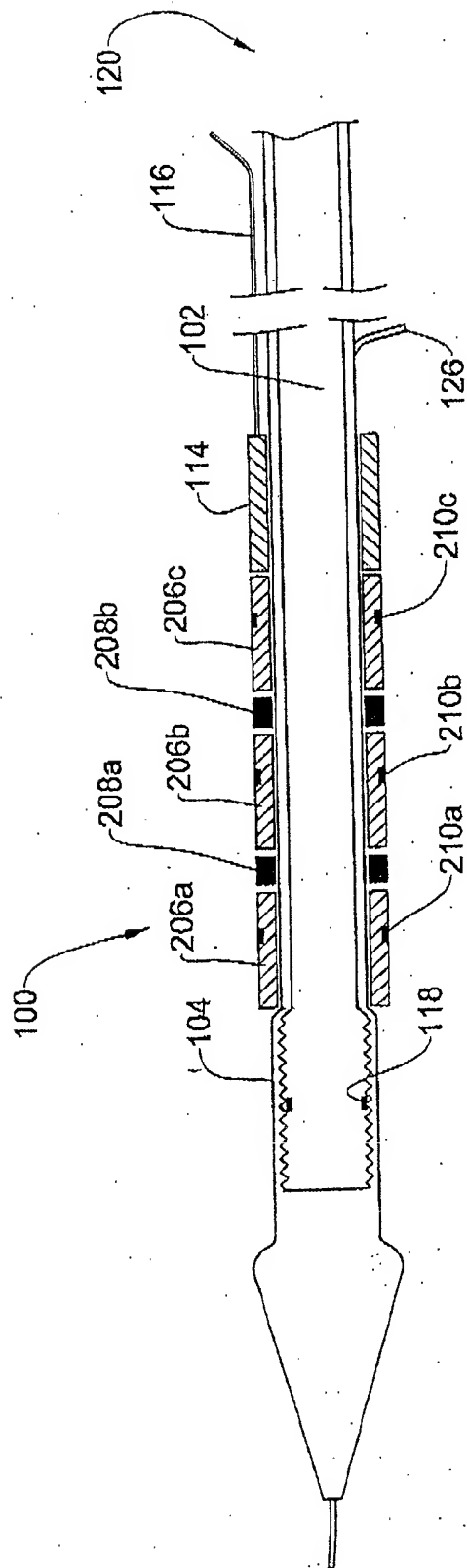


FIG. 2

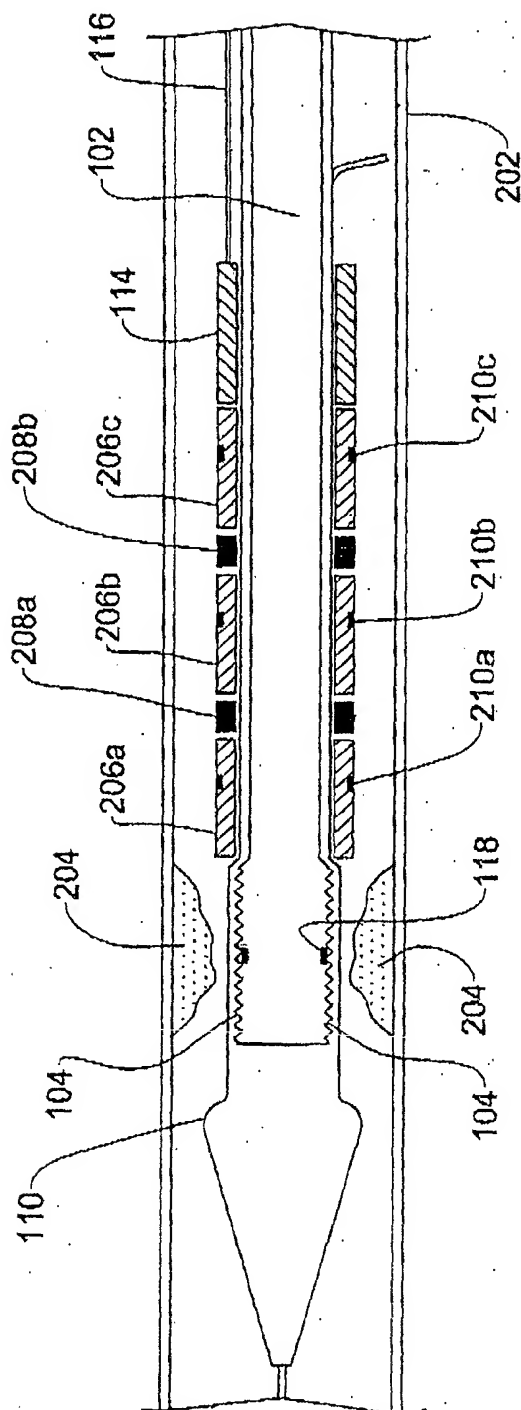


FIG. 3

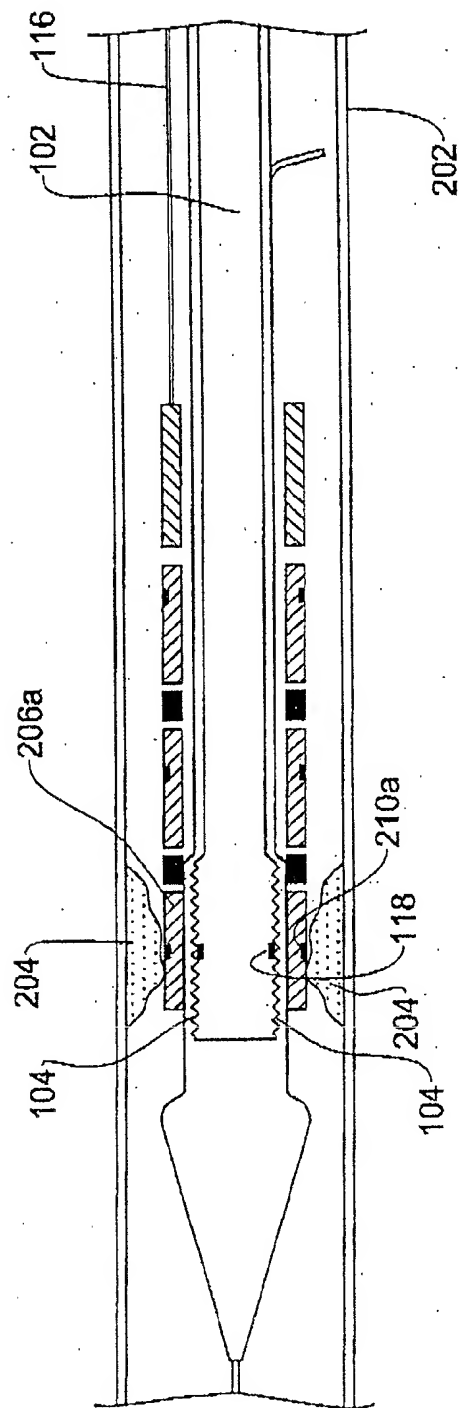


FIG. 4

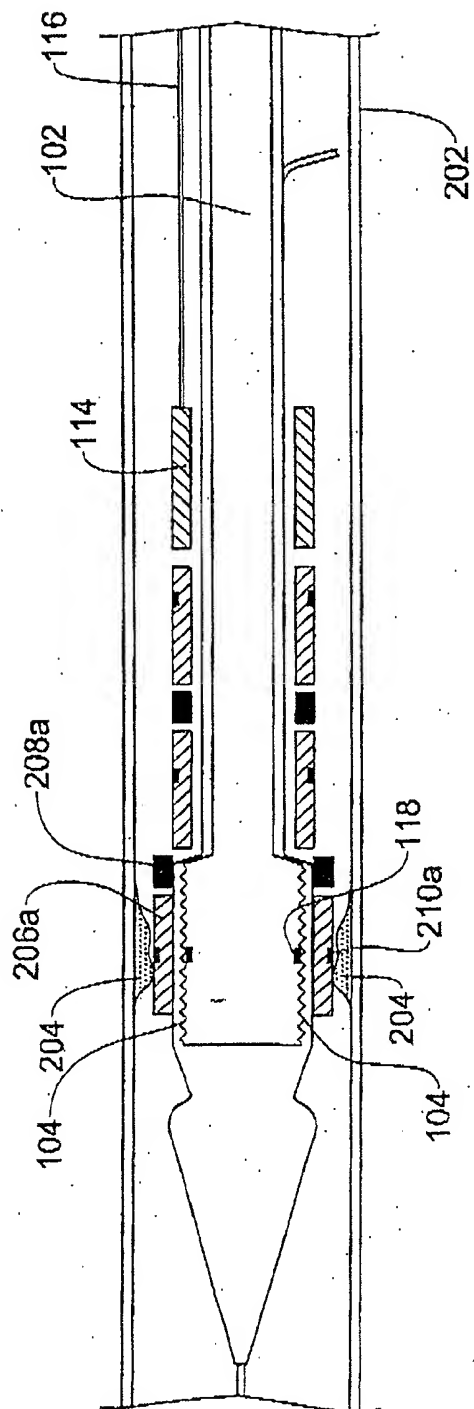


FIG. 5

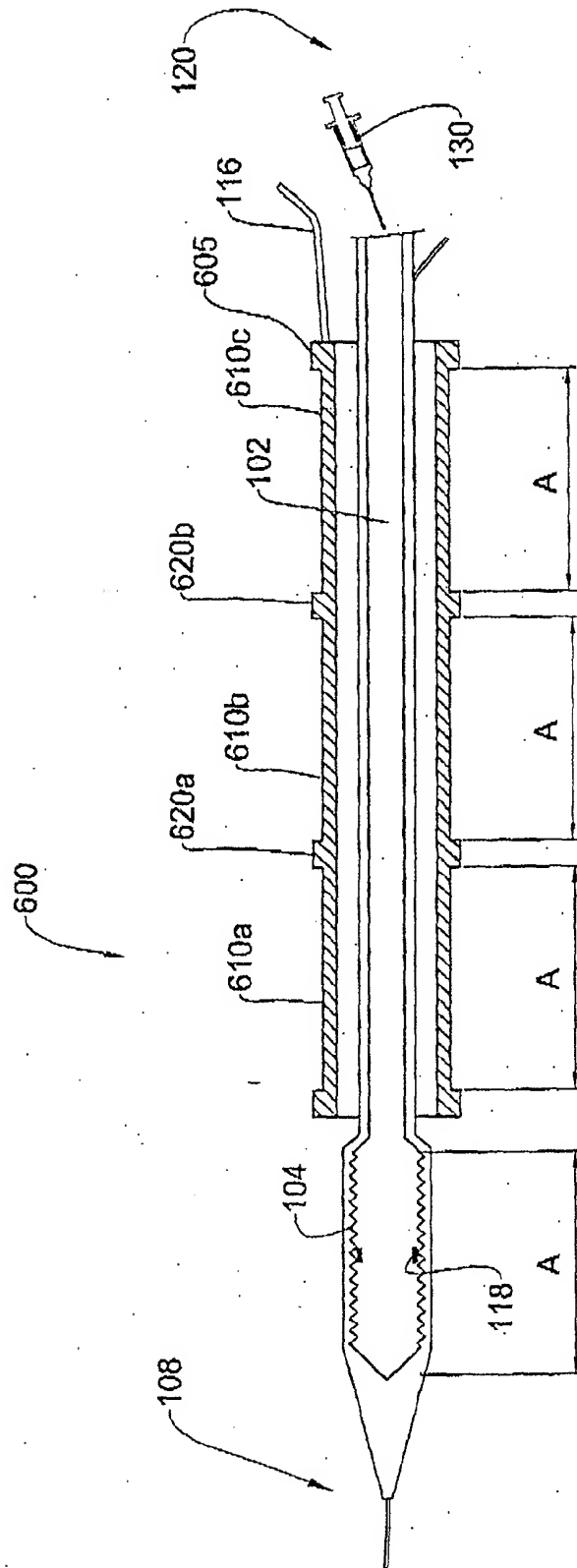


FIG. 6

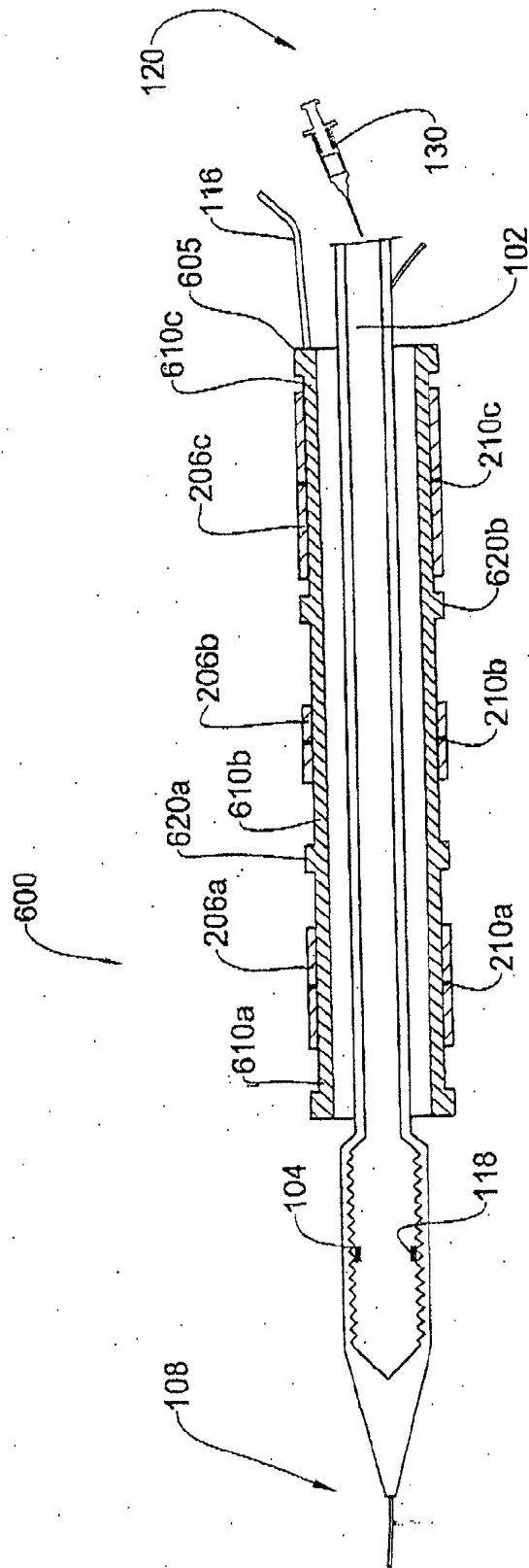
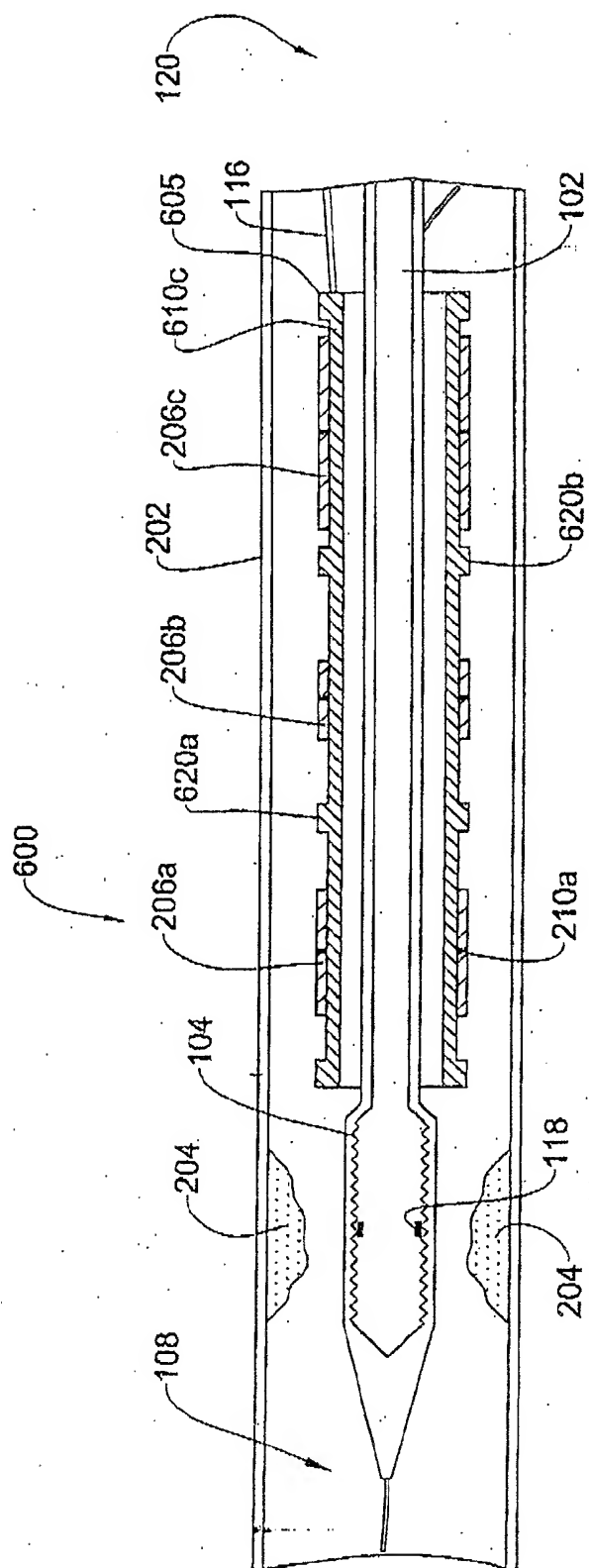


FIG. 7



FG 8

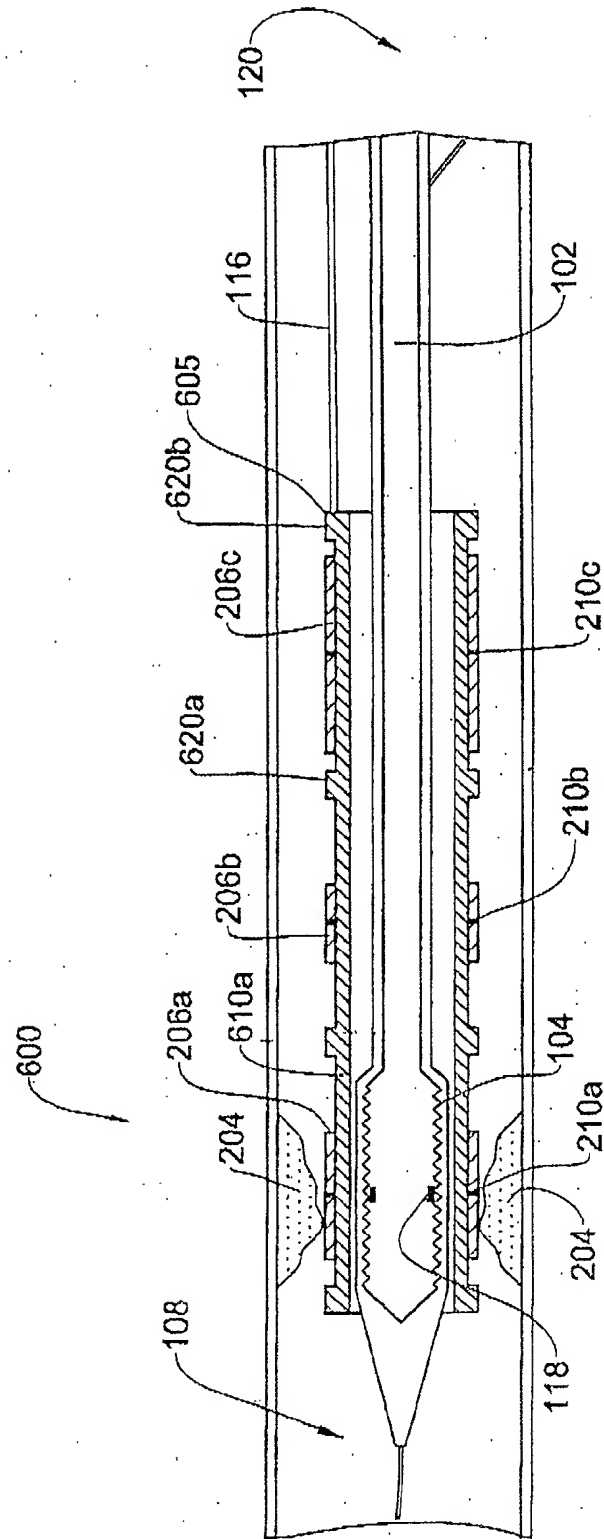


FIG. 9

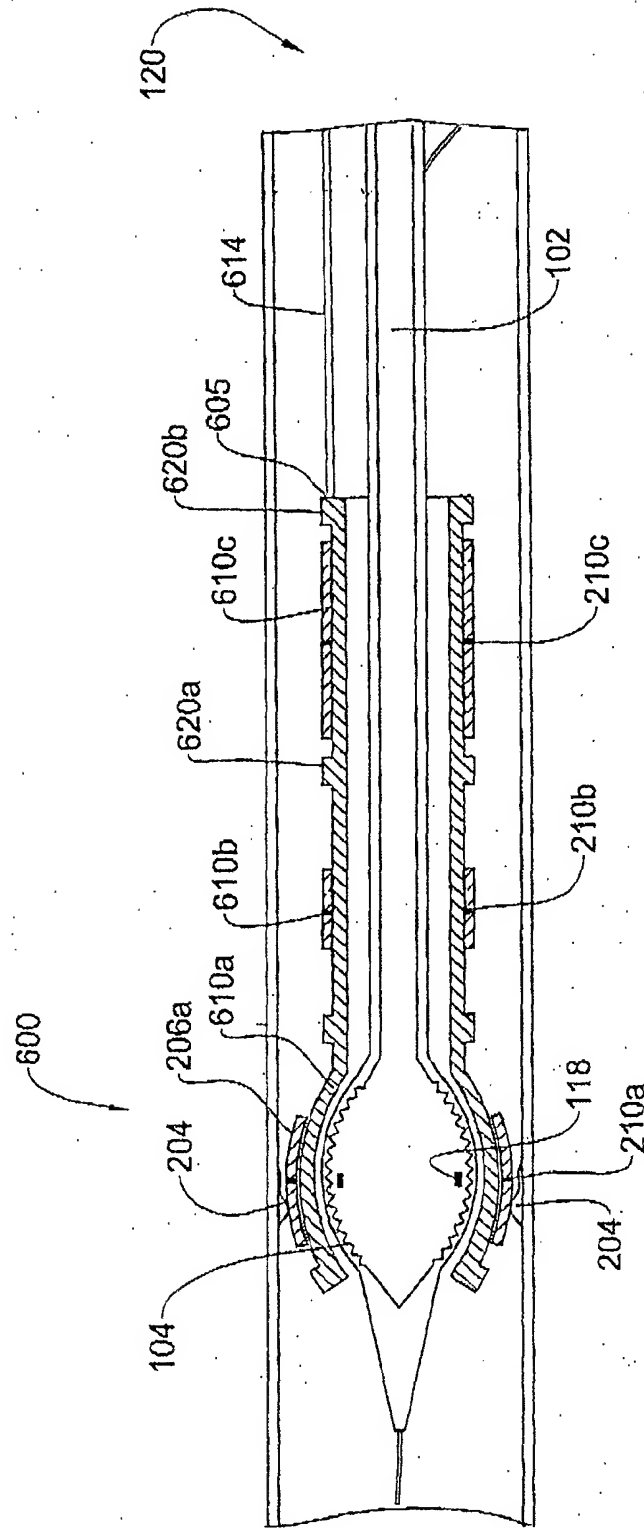


FIG. 10

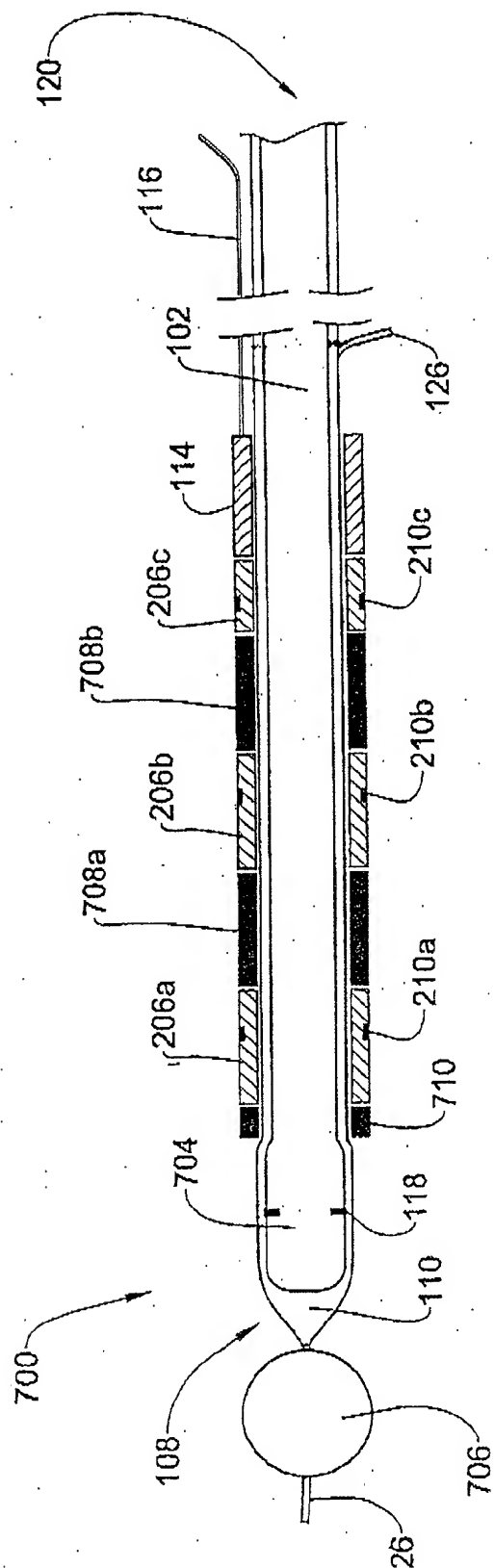


FIG. 11

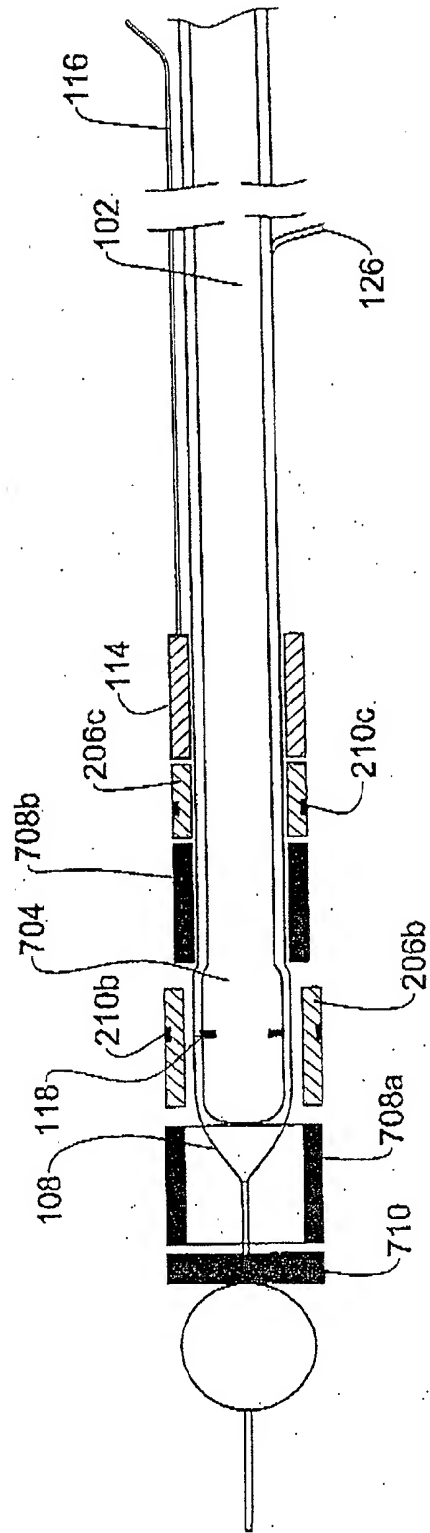


FIG. 12

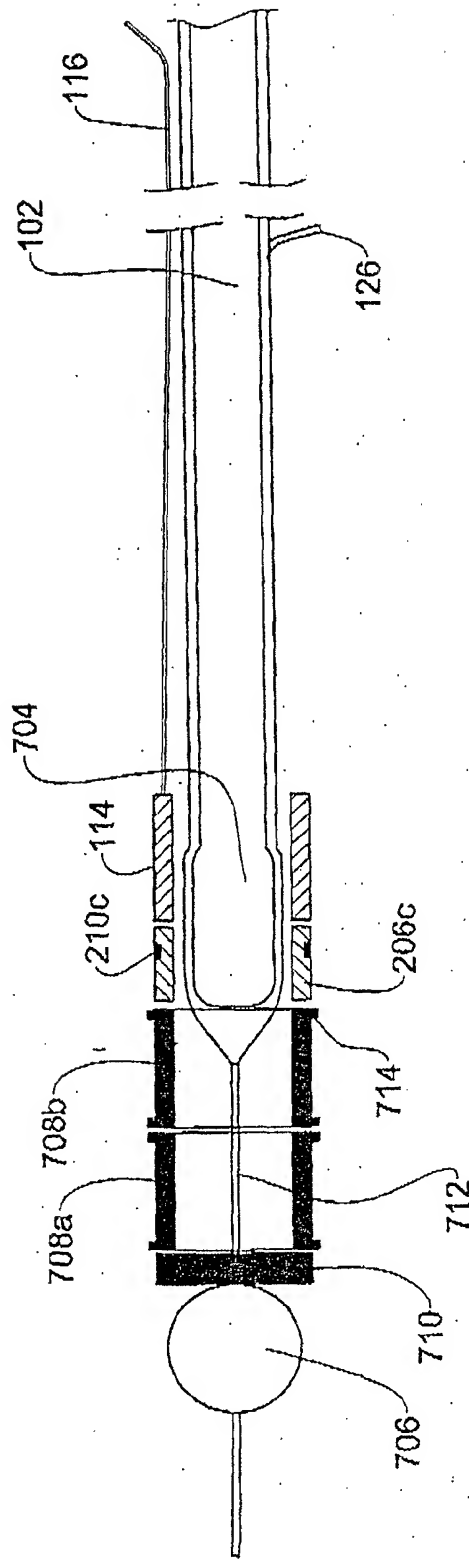


FIG. 13